

AMENDMENTS TO THE CLAIMS

Please amend the claims as set out in the listing below.

1. (Currently amended) A method of predicting the likelihood of long-term survival of ~~an~~ without recurrence of breast cancer for a patient having estrogen receptor (ER)-positive breast cancer patient without the recurrence of breast cancer, the method comprising:

(a) assaying an expression level of an RNA transcript or its expression product in a biological sample comprising a breast cancer cell obtained from the patient, wherein the RNA transcript is a MYBL2 transcript;

(b) determining [(the)] a normalized expression level of the MYBL2 RNA transcript of MYBL2 or its expression product, in an ER-positive breast cancer tissue sample obtained from said patient, normalized against the expression level of all RNA transcripts or their products in said breast cancer tissue sample, or of a reference set of RNA transcripts or their expression products and wherein the normalized expression level of the MYBL2 transcript or its expression product positively correlates with an increased likelihood of breast cancer recurrence in the patient; and

(b) (c) providing prognostic information to the patient containing regarding an estimate of the likelihood of long-term survival without breast cancer recurrence in said for the patient, wherein the information comprises the normalized expression level of the MYBL2 transcript or its expression product expression of the RNA transcript of MYBL2 or its expression product is an indication of a decreased likelihood of long-term survival without breast cancer recurrence.

2. – 5. (Canceled)

6. (Original) The method of claim 1 wherein breast cancer is invasive breast carcinoma.

7. (Canceled)

8. (Currently amended) The method of claim 1 wherein ~~said the biological sample RNA~~ is isolated from a fixed, wax-embedded breast cancer tissue specimen of said patient.

9. (Currently amended) The method of claim 1 wherein ~~said RNA~~ the biological sample is isolated from core biopsy tissue or fine needle ~~aspirate~~ aspirated cells.

10-24. (Canceled)

25. (Currently amended) A method of preparing a personalized genomics profile for a patient with estrogen receptor (ER)-positive breast cancer, comprising the steps of:

(a) ~~subjecting RNA extracted from an estrogen receptor (ER)-positive breast tissue~~ assaying an expression level of an RNA transcript or its expression product in a biological sample comprising a breast cancer cell obtained from the patient ~~to gene expression analysis,~~ wherein the RNA transcript is a MYBL2 transcript;

(b) determining [[the]] a normalized expression level of the RNA MYBL2 transcript of MYBL2 or its expression product, ~~wherein the expression level is normalized against a control gene or genes and optionally is compared to the amount found in a breast cancer reference tissue set~~ wherein the normalized expression level of the MYBL2 transcript or its expression product positively correlates with an increased likelihood of breast cancer recurrence in the patient; and

(c) creating a report summarizing ~~the data obtained from the normalized expression level by said gene expression analysis, and containing an estimate of likelihood of long term survival without cancer recurrence in said patient, wherein expression of the RNA transcript of MYBL2 or its expression product is considered an indication of a decreased likelihood of long term survival without breast cancer recurrence.~~

26. (Canceled)

27. (Currently amended) The method of claim [[26]] 25, wherein ~~said breast tissue~~ the biological sample is ~~obtained from~~ a fixed, paraffin-embedded biopsy sample.

28. (Currently amended) The method of claim [[27]] 25 wherein ~~said~~ the RNA transcript is fragmented.

29. (Canceled)

30. (Currently amended) The method of claim 25 ~~further comprising wherein said report further comprises a recommendation for a treatment modality of said patient~~ identifying a treatment option for the patient based on the normalized expression level.

31-35. (Canceled)

36. (Currently amended) The method of claim 1 wherein the expression level of the MYLB2 transcript, or its expression product, is normalized against a ~~[[the]]~~ reference set of RNA transcripts or their expression products ~~comprises the~~ comprising RNA transcripts of two or more housekeeping genes, or their expression products.

37. (Currently Amended) The method of claim 36 wherein the two or more housekeeping genes are selected from the group consisting of glyceraldehyde-3-phosphate dehydrogenase (GAPDH), Cyp1, albumin, actins, tubulins, cyclophilin, hypoxanthine phosphoribosyltransferase (HRPT), L32, 28S, and 18S.

38. - 55. (Canceled)

56. (Withdrawn- currently amended) The method of claim 1, further comprising (a) assaying an expression level of at least one RNA transcript or its expression product in a biological sample comprising at least one breast cancer cell obtained from the patient, wherein the at least one RNA transcript is the transcript of a gene selected from the group consisting of: GRB7, CTSL, CD68, Chk1, AIB1, CCNB1, MCM2, FBXO5, STK15, SURV, EGFR, HIF1 α , and TS;

(b) determining the a normalized expression level of one or more the RNA transcripts transcript or their its expression products product in a breast cancer tissue sample obtained from said patient, normalized against the expression level of all RNA transcripts or their products in said breast cancer tissue sample, or of a reference set of RNA transcripts or their expression products, wherein the RNA transcript is the transcript of one or more genes selected from the

group consisting of: TP53BP2, Bcl2, KRT14, IRS1, GRB7, CTSL, CD18, EstR1, Chk1, IGFBP2, BAG1, CEGP1, STK15, GSTM1, FHIT, RIZ1, AIB1, SURV, BBC3, IGF1R, p27, GATA3, ZNF217, EGFR, CD9, HIF1 α , pS2, ErbB3, TOP2B, MDM2, RAD51C, KRT19, TS, KLK10, β -Catenin, γ -Catenin, MCM2, P13KC2A, IGF1, TBP, CCNB1, FBXO5, and DR5, wherein the normalized expression level of the RNA transcript or its expression product positively correlates with an increased likelihood of breast cancer recurrence; and

(c) providing information comprising the likelihood of long-term survival without breast cancer recurrence for the patient, wherein the information comprises the normalized expression level of the RNA transcript or its expression product.

57. (Withdrawn- currently amended) The method of claim [[56]] 1, further comprising

(a) assaying an expression level of at least one RNA transcript or its expression product in a biological sample comprising at least one breast cancer cell obtained from the patient, wherein the at least one RNA transcript is the transcript of a gene selected from the group consisting of: TP53BP2, Bcl2, KRT14, EstR1, IGFBP2, BAG1, CEGP1, KLK10, β -Catenin, γ -Catenin, DR5, P13KCA2, RAD51C, GSTM1, FHIT, RIZ1, BBC3, TBP, p27, IRS1, IGF1R, GATA3, ZNF217, CD9, pS2, ErbB3, TOP2B, MDM2, IGF1, and KRT19;

(b) determining a normalized expression level of the at least one RNA transcript or its expression product, wherein ~~expression of one or more of GRB7, CTSL, CD68, Chk1, AIB1, CCNB1, MCM2, FBXO5, STK15, SURV, EGFR, HIF1 α , and TS indicates a decreased~~ likelihood of long-term survival without breast cancer recurrence, and the expression of one or more of TP53BP2, Bcl2, KRT14, EstR1, IGFBP2, BAG1, CEGP1, KLK10, β -Catenin, γ -Catenin, DR5, P13KCA2, RAD51C, GSTM1, FHIT, RIZ1, BBC3, TBP, p27, IRS1, IGF1R, GATA3, ZNF217, CD9, pS2, ErbB3, TOP2B, MDM2, IGF1, and KRT19 indicates an increased likelihood of long-term survival without breast cancer recurrence the normalized expression level of the at least one RNA transcript or its expression product negatively correlates with an increased likelihood of breast cancer recurrence.

58. (Withdrawn - currently amended) The method of claim 1 further comprising determining the normalized expression level of ~~prognostic RNA transcripts a PR RNA transcript~~ or their its expression products product of PR, wherein the ~~expression of PR indicates an~~

increased likelihood of long-term survival without breast cancer recurrence the normalized expression level of PR negatively correlates with an increased likelihood of breast cancer recurrence.

59. (Withdrawn - currently amended) The method of claim [[58]] 1 further comprising determining [[the]] a normalized expression level of prognostic RNA transcripts a Her2 RNA transcript or their its expression products product of Her2, wherein the normalized expression level of Her2, indicates a decreased likelihood of long-term survival without breast cancer recurrence negatively correlates with an increased likelihood of long-term survival without breast cancer recurrence .

60. (Withdrawn – currently amended) The method of claim 1 further comprising in step (a) determining the expression level of the PR RNA transcript ~~of PR~~ or its expression product in a breast cancer tissue sample obtained from said patient, normalized against the expression levels of all RNA transcripts or their expression products in said breast cancer tissue sample, or of a reference set of RNA transcripts or their products.

61. (Withdrawn – currently amended) The method of claim 1 or claim 60 further comprising in step (a) determining the expression level of the Her2 RNA transcript ~~of Her2~~ or its expression product in a breast cancer tissue sample obtained from said patient, normalized against the expression levels of all RNA transcripts or their expression products in said breast cancer tissue sample, or of a reference set of RNA transcripts or their products.

62. (Withdrawn) The method of claim 25 further comprising in step (b) determining the expression level of PR, wherein the expression level is normalized against a control gene or genes and optionally is compared to the amount found in a breast cancer reference tissue set.

63. (Withdrawn) The method of claim 25 or claim 62 further comprising in step (b) determining the expression level of Her2 wherein the expression level is normalized against a control gene or genes and optionally is compared to the amount found in a breast cancer reference tissue set.

64.– 66. (Canceled)

67. (New) The method of claim 1, wherein the information is provided in the form of a report.

68. (New) The method of claim 56, wherein the information is provided in the form of a report.